

Pharmacy



Prior Authorization Criteria for the PDE-5 Inhibitors

The phospohdiesterase-5 (PDE-5) inhibitors for erectile dysfunction include vardenafil (Levitra,Staxyn), sildenafil (Viagra), avanafil (Stendra) and tadalafil (Cialis). All of these agents (except Stendra) are used for a variety of conditions, including erectile dysfunction, pulmonary hypertension, Raynaud's phenomenon, benign prostatic hyperplasia, and post-prostatectomy. Two other agents, Revatio (sildenafil) and Adcirca (tadalafil) are marketed specifically for primary pulmonary hypertension. The DOD Pharmacy and Therapeutics Committee designated this class as subject to prior authorization.

Prior authorization for PDE-5 inhibitors is NOT required for male patients 40 years of age or older being treated for erectile dysfunction with Viagra. Prior authorization IS required for male patients less than 40 years of age being treated for erectile dysfunction, for ALL new erectile dysfunction patients being treated with Cialis, Staxyn, Levitra, or Stendra and for ALL patients being treated for primary pulmonary hypertension, Raynaud's phenomenon, benign prostatic hyperplasia, and post-prostatectomy uses.

Coverage IS provided for:

- PDE-5 inhibitors for male patients 18 to 39 years of age with an approved prior authorization for:
 - · Organic erectile dysfunction (e.g., diabetes-related, vascular-related); or
 - Mixed organic/psychogenic erectile dysfunction; or
 - Drug-induced erectile dysfunction where the causative drug cannot be altered or discontinued.
- PDE-5 inhibitors for male patients with erectile dysfunction, 40 years of age and older.
 - Sildenafil (Viagra) no prior authorization form required
 - Vardenafil ODT (Staxyn), vardenafil (Levitra), avanafil (Stendra) or tadalafil (Cialis) step therapy PA applies (See criteria below).
- Sildenafil (Revatio or Viagra) or tadalafil (Cialis or Adcirca) for any patient with primary pulmonary hypertension. Sildenafil (Viagra) vardenafil (Levitra) or tadalafil (Cialis) for any patient with Raynaud's phenomenon or for preservation and/or restoration of erectile function post-prostatectomy. Note the usage for preservation/restoration of erectile function is limited to one year after surgery.
- Tadalafil 5 mg (Cialis 5mg) for patients with benign prostatic hyperplasia (BPH) meeting prior authorization criteria listed below.

Prior Authorization Criteria for Cialis (tadalafil) 5mg for BPH

All current and new users of Cialis (tadalafil) 5 mg daily (for BPH) must meet one of the following criteria in order for Prior Authorization to be approved:

- 1. Diagnosis of benign prostatic hyperplasia (BPH)
- 2. Dosage is 5 mg daily
- Patient tried tamsulosin (Flomax) or alfuzosin (Uroxatral) and had an inadequate response.
- 4. Patient tried tamsulosin (Flomax) or alfuzosin (Uroxatral) and was unable to tolerate it due to adverse effects.
- 5. Treatment with tamsulosin (Flomax) or alfuzosin (Uroxatral) is contraindicated (for example due to hypersensitivity).

Coverage IS NOT provided for:

- Female sexual dysfunction, or
- Erectile dysfunction in males under 18 years of age, or
- Psychogenic erectile dysfunction

Quantity Limits

- Treatment of Erectile Dysfunction The PDE-5 inhibitors are limited to a maximum of 18 tablets per 90 days from the MOP or 6 tablets per 30 days from retail network pharmacies. This quantity limit applies collectively to all three medications. This means that no more than 18 tablets per 90-day supply of any combination of these medications will be dispensed in the TRICARE Mail Order Pharmacy and no more than 6 tablets per 30-day supply of any combination of these medications will be dispensed by retail network pharmacies. (Note: Staxyn (vardenafil ODT) is available in packages of four (4) tablets each. The Mail Order Pharmacy cannot break packaging and must dispense this product in multiples of 4.)
- Treatment of Pulmonary Arterial Hypertension, Raynaud's phenomenon, post-prostatectomy preservation/restoration of erectile function, Benign Prostatic Hyperplasia (BPH) Usual rules apply (90-day supply in the MOP or 30-day supply at retail network pharmacies, based on the directions for use on the prescription).
- Use of Multiple Pharmacy Points of Service The amount of medication obtained by a patient from all Military Health System pharmacy points of service will be taken into account in the application of this quantity limit.

Medical necessity forms are available on the TRICARE Pharmacy website at http://tricare.mil/Pharmacy/Drugs.aspx

Criteria approved through the Uniform Formulary decision-making process.

www.tricare.mil is the official Web site of the Defense Health Agency, a component of the Military Health System 7700 Arlington BLVD, Falls Church, VA 22042

Viagra (sildenafil) Prior Authorization Request Form



5669

Page 1 of 2

To be completed and signed by the prescriber. To be used only for prescriptions which are to be filled through the Department of Defense (DoD) TRICARE pharmacy program (TPHARM). Express Scripts is the TPHARM contractor for DoD.

MAIL ORDER and RETAIL The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477

 The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to:

TpharmPA@express-scripts.com

Prior authorization criteria and a copy of this form are available at http://pec.ha.osd.mil/forms_criteria.php. This prior authorization has no expiration date.

| Step | Please complete patient and physician information (please print): | | | | |
|-----------|--|------------------------------|-------------------------------|--|--|
| 1 | Patient Name: | Physician Name: | | | |
| • | Address: | Address: | | | |
| | | | | | |
| | Sponsor ID # | Phone #: | | | |
| | Date of Birth: | Secure Fax #: | | | |
| Step 2 | Please consider the following: Patients taking nitrates, either regularly or intermittently, should not receive PDE-5 inhibitors. Patients should be informed of the consequences should they initiate nitrate therapy while taking a PDE-5 inhibitor. Please see product labeling precautions for concurrent use with alpha blockers. | | | | |
| Step 3 | Please indicate the patient's gender. | | | | |
| | Female | Please go to Section 1 for | Female patients on this page | | |
| | Male | Please go to Section 2 for | Male patients on page 2 | | |
| | Section 1 – Female patients | | | | |
| | Is the PDE-5 inhibitor being prescribed for the treatment of sexual dysfunction? | ☐ Yes Coverage not approved | □ No Proceed to Question 2 | | |
| | 2. Is the PDE-5 inhibitor being prescribed for a diagnosis of pulmonary arterial hypertension (PAH)? | ☐ Yes Proceed to Question 4 | □ No Proceed to Question 3 | | |
| | 3. Is the PDE-5 inhibitor being prescribed for a diagnosis of Raynaud's phenomenon? | ☐ Yes Proceed to Question 4 | □ No Coverage not approved | | |
| | 4. What is the dosing regimen? | | | | |

Please go to Step 4 on Page 2.

Viagra (sildenafil) Prior Authorization Request Form



5670

Page 2 of 2

| Section 2 – Male patients | | | | | |
|--|--|-------------------------------|--|--|--|
| 1. Is the patient 18 years of age or older? | ☐ Yes Proceed to Question 2 | □ No Proceed to Question 7 | | | |
| 2. Is the patient 40 years of age or older? | ☐ Yes Do not submit form. Prior authorization is not required for males 40 years or older. | □ No Proceed to Question 3 | | | |
| 3. Is Viagra being prescribed for the treatment of erectile dysfunction of organic origin or mixed organic/psychogenic origin? | ☐ Yes Sign and date below | □ No Proceed to Question 4 | | | |
| 4. Is Viagra being prescribed for the treatment of drug-induced erectile dysfunction where the causative drug cannot be altered or discontinued? | ☐ Yes Sign and date below | ☐ No Proceed to Question 5 | | | |
| 5. Is Viagra being prescribed for preservation or restoration of erectile function following prostatectomy? | ☐ Yes SKIP to Question 8 ¹ | □ No Proceed to Question 6 | | | |
| 6. Is Viagra being prescribed for a diagnosis of Raynaud's phenomenon? | ☐ Yes SKIP to Question 8 | □ No Proceed to Question 7 | | | |
| 7. Is Viagra being prescribed for a diagnosis of pulmonary arterial hypertension (PAH)? | ☐ Yes Proceed to Question 8 | □ No Coverage not approved | | | |
| 8. What is the dosing regimen? | | | | | |
| ¹ Authorizations for preservation/restoration after prostatectomy | are valid for 1 vear. | | | | |

| Step | I certify the above is correct and accurate to the best of my knowledge. Please sign and date: | | | | |
|------|--|------|--|--|--|
| 4 | | | | | |
| | Prescriber signature | Date | | | |

[24 Dec 2013]